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09/435992

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
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1644

18

DATE MAILED:

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 4/16/01 ; 9/4/01

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 1-41, 57-59 is/are pending in the application.  
Of the above, claim(s) 3-5, 14-17, 28-31, 36-41 is/are withdrawn from consideration.  
☐ Claim(s) \_\_\_\_\_ is/are allowed.  
☒ Claim(s) 1, 2, 6-13, 18-27, 32-35, 57-59 is/are rejected.  
☐ Claim(s) \_\_\_\_\_ is/are objected to.  
☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.  
☐ The specification is objected to by the Examiner.  
☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.  
☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☒ Notice of Reference Cited, PTO-892  
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
☐ Interview Summary, PTO-413  
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948  
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Serial No. 09/435992  
Art Unit 1644

### DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Technology Center 1600.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1- 41, drawn to methods of treating B cell malignancies with CD40L-specific antibodies alone in combination with other CD40-/CD20-specific antibodies or chemotherapeutic agents, classified in Class 424, subclass 130.1

II. Claims 42-56, drawn to compositions of CD40L-specific antibodies and other CD40-/CD20-specific antibodies or chemotherapeutic agents, classified in Class 424, subclass 130.1.

3. Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, malignancies such as B cell lymphomas/leukemias are treated with a variety of chemotherapeutic and radiotherapeutic reagents, which do not include CD40L-specific antibodies.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II and Groups I and II have acquired a separate status in the art as shown by their divergent subject matter, restriction for examination purposes as indicated is proper.

5. This application contains claims directed to the following patentably distinct species of the claimed Group I : wherein the following is administered.

- A) CD40L-specific antibody,
- B) CD40L-specific antibody and a second antibody (e.g. claim 10; CD20-specific antibody),
- C) CD40L-specific antibody and a chemotherapeutic (e.g. claim 10)
- D) CD40L-specific antibody and radiotherapy (e.g. claim 10), or
- E) combinations of CD40L-specific antibodies with a second antibody, a chemotherapeutic or radiotherapy.

These species are distinct because the ingredients differs in structures, physicochemical properties and modes of actions. Therefore, they are separate and patentably distinct species

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

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Art Unit 1644

If applicant elects combinations (E); then applicant should elect a particular combination (e.g. CD40L-specific antibody and CD20-specific antibody and a chemotherapeutic).

6. This application contains claims directed to the following patentably distinct species of the claimed Group II : wherein the composition comprises:

- A) CD40L-specific antibody and a radiolabeled CD40L-specific antibody,
- B) CD40L-specific antibody and a radiolabeled CD20-specific antibody,
- C) CD40L-specific antibody and a CD20-specific antibody,
- D) CD40L-specific antibody and combinations of (A), (B), (C), or
- E) combinations of CD40L-specific antibodies with (A), (B), (C), (D) with or without chemotherapeutic agents.

These species are distinct because the ingredients differs in structures, physicochemical properties and modes of actions. Therefore, they are separate and patentably distinct species

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 42 is generic.

7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

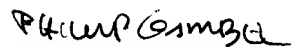
8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

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9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

  
Phillip Gambel, PhD.  
Primary Examiner  
Technology Center 1600  
March 12, 2001